DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

d19506

Certified/Return Receipt Requested

Food and Drug Administration
Kansas City District Office
11630 West 80th Street
P.O. Box 15905
Lenexa, Kansas 66285-5905

Telephone: (913) 752-2100

July 29, 1998

# WARNING LETTER

Dr. Gary D. Hindman, Ph.D.
Vice President/General Manager
Ivy Laboratories, Inc.
8857 Bond Street
Overland Park, KS 66214

Ref. # - KAN-98-022

Dear Dr. Hindman:

During an inspection of your veterinary drug manufacturing facility located at the above address, conducted on June 25 to July 1, 1998, our investigators found significant deviations from the Good Manufacturing Practice for Finished Pharmaceuticals regulations (21 CFR, Part 211). Such deviations cause veterinary drugs being manufactured at this facility to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (Act).

Our investigation found, among others, failure to thoroughly validate your recirculating air handling and dust collection systems which services drug production areas; failure to perform adequate process validation for the product "TE-S"; and failure to perform an adequate calibration program for processing equipment requiring calibration.

The above is not intended to be an all-inclusive list of violations. As a manufacturer of veterinary drugs, you are responsible for assuring that your overall operation and the products you manufacture and distribute are in compliance with the law. At the conclusion of the inspection a Form FDA 483, Inspectional Observations, was issued to and discussed with you. This form is a comprehensive listing of the investigators' observations of deviations found during the inspection. You should take prompt action to correct these violations and to establish procedures to prevent their recurrence.

We acknowledge that you have submitted to this office a response dated July 16, 1998, concerning our investigators' observations noted on the Form FDA 483. We are reviewing your response and will provide you our comments under a separate letter.

Federal agencies are advised of the issuance of all Warning Letters about drugs so that they may take this information into account when considering the award of contracts. You should take prompt action to correct these deviations. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

You should notify this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. You may address your reply to Clarence R. Pendleton, Compliance Officer, at the above address.

Sincerely,

W. Michael Rogers
District Director
Kansas City District

cc: James Sollins, President
Ivy Laboratories, Inc.
55 Greene Street
New York City, NY 10013